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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/919,770      | 07/31/2001  | Paul Bornstein       | UOPW117618          | 4001             |

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC  
1420 FIFTH AVENUE  
SUITE 2800  
SEATTLE, WA 98101-2347

EXAMINER

GIBBS, TERRA C

AGENT PAPER NUMBER

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                  |  |
|------------------------------|-------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/919,770 | Applicant(s)<br>BORNSTEIN ET AL. |  |
|                              | Examiner<br>Terra Gibbs       | Art Unit<br>1635                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-27 are pending in the instant application.

#### ***Oath/Declaration***

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). For example, the second inventor changed their zip code without proper initial and dating and the last inventor changed their citizenship without proper initial and dating. Appropriate correction is required.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 10 and 12-18, drawn to a method of modulating the amount or biological activity of thrombospondin 2 or osteopontin in an animal, said method comprising the step of introducing into the animal an amount of a molecule, selected from the group consisting of osteopontin and a thrombospondin 2 antagonist, effective to modulate the amount or biological activity of thrombospondin 2 or osteopontin in the animal, wherein the molecule is an antisense thrombospondin 2 nucleic acid or a thrombospondin 2 ribozyme, classified in class 514 subclass 44 and class 536, subclass 24.5.
- II. Claims 1-3, 8 and 12-18 drawn to an anti-thrombospondin 2 antibody, classified in class 424, subclass 130.1.

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- III. Claims 1-3, 9 and 12-18, drawn to a thrombospondin 2 blocking peptide, classified in class 530, subclass 395.
- IV. Claims 19-27, drawn to a medical device comprising: a device body; and a surface layer attached to the device body, said surface layer comprising an amount of an agonist or antagonist of a matricellular protein sufficient to reduce the foreign body response against the device, wherein said device is adapted to be affixed to, or implanted within, the soft tissue of an animal, classified in class 623, subclass 1.1.

Claims 1-3 and 12-18 are generic to the Groups I-III. Claims 1-3 and 12-18 will be examined limited to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of modulating the amount or biological activity of thrombospondin 2 or osteopontin in an animal, said method comprising the step of introducing into the animal an amount of a molecule, selected from the group consisting of osteopontin and a thrombospondin 2 antagonist, effective to modulate the amount or biological activity of thrombospondin 2 or osteopontin in the animal; different antagonists of thrombospondin 2, including thrombospondin 2 antisense, an anti-thrombospondin 2 antibody, a thrombospondin 2 blocking peptide and a thrombospondin 2 ribozyme; and a medical device

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comprising: a device body; and a surface layer attached to the device body, said surface layer comprising an amount of an agonist or antagonist of a matricellular protein sufficient to reduce the foreign body response against the device, wherein said device is adapted to be affixed to, or implanted within, the soft tissue of an animal; such that each different invention requires materials and method steps, technologies and search of a body of prior art, that are distinctly different from those required for each of the others such that each different invention would require a separate classification search (e.g. an antisense cannot function as an antibody; an antisense cannot function as a peptide; and an antibody cannot be substituted for a ribozyme).

Inventions of Group I-III and the invention of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the molecules of Groups I-III can be used as thrombospondin 2 antagonists of Group IV, drawn to a medical device comprising a first surface layer comprising osteopontin; and a second surface layer comprising a thrombospondin 2 antagonist.

These inventions are not disclosed as capable of use together and are independent and distinct because the different antagonists of Groups I-III have different molecular structures that result in different functions and effects each from the other. Furthermore, the medical device of Group IV is a separate entity from the method of modulating the amount or biological activity of thrombospondin 2 or osteopontin in an animal, said method comprising the step of introducing into the animal an amount of a molecule, selected from the group consisting of osteopontin and a

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thrombospondin 2 antagonist, effective to modulate the amount or biological activity of thrombospondin 2 or osteopontin in the animal, of Groups I-III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, because a separate search would be required for each one of the different thrombospondin 2 antagonists, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg  
August 2, 2002



SEAN MCGARRY  
PRIMARY EXAMINER  
1635